In the United States Patent and Trademark Office

Application of: John B. McCraw) Examiner Hand, Melanie Jo
Prior Serial Number: 10/715,549) Art unit 3761
Prior Filing: 11/17/2003)
Entitled: APPARATUS AND METHOD FOR DRAINAGE

Commissioner for Patents
PO Box 1450
Alexandria, VA22313-1450
Dear Sir:

SECTION 132 AFFIDAVIT OF THE INVENTOR John B. McCraw

John B. McCraw being sworn states:

I am a nationally recognized surgical expert in wound healing and a M.D., a Fellow of the American College of Surgery, and currently a Professor Plastic Surgery at The University of Mississippi Medical Center Department of Surgery.

I have made my living as a practicing physician and surgeon since completing training in general surgery and plastic surgery in 1973.

During that period, 1973 to 2005, most of my efforts were related to patient care of those that sought surgical treatment, and I am thoroughly familiar with surgical techniques and recovery procedures after surgery.

I have used all of the many different types of surgical drains and placed them in patients during surgery and have watched the healing process with the use of the available drains, and I am aware of the trauma and difficulties encountered when each was used. I am aware of the deficiencies of these drains, including frequent clotting of the cylindrical tube with subsequent failure to drain the wound, which can lead to a hematoma, seroma, or loss of skin.

I am the inventor of the drainage apparatus, method of using it and method of making it disclosed and claimed in the above identified patent application and am thoroughly familiar with the patent application, the office action and this reply including the cited references and amended claims.

I was familiar with the patent references cited by the Examiner as those were found and reviewed by me during the process of preparing this patent application.

I know that those references uniformly teach the use of percutaneous (through the tissue) tubing or supporting structures to hold the wound or surgical site open

for drainage and that tubing or supporting structures are traumatic and that the failure of these drains through clotting may inhibit the healing process.

I was the first to recognize and understand that flexible fibers **without any surrounding tubing or supporting structures** could be used as an effective drain for removal of fluids from within the wound.

In this method simple off-the-shelf absorbable suture strands are passed percutaneously (through the skin) and serve to maintain the opening from the wound to the surface of the skin. Within the wound the suture strands are spread out within the surgical site, and this attracts fluid to opening in the skin. The suture strands then pass through a minimal exit opening through the skin, that is, just for the flexible fibers, and afford a path for guiding drainage of fluids from the wound.

I have found that a minimal opening about the flexible fibers heals better and quicker and is less traumatic than drains with tubing or supporting structures, and that the flexible fibers guide drainage while the opening heals naturally without any additional trauma caused by propping open an exit with tubing or support structures.

I recognized that the flexible fibers can be easily removed from the patient without discomfort. The degradable fibers can also remain in the wound and be allowed to become biologically absorbed within the wound without harm to the patient.

Not one, of the proffered or cited references (relied on or not), disclose any understanding of my claimed flexible fiber drain that functions without tubing or support structure placed through the tissue exit.

My apparatus, and methods for the flexible fibers drain was disclosed and claimed in my above application as filed.

I participated in the preparation of the above patent application and believe that the Examiner's conclusions about my claims being anticipated and obvious is contrary to prevailing practice of skilled artisans wherein tubing or support structure remains in the patient's tissue as an exit for drainage and that particularly with respect to those traumatic apparatus and methods there is no teaching like my drain with only flexible fibers that also spread out within the surgical site.

I believe that I was the first to understand and apply the now claimed apparatus and method of drainage without tubing or supporting structure to hold open a path from the surgery to the outside.

I believe that the concepts of no supporting structure and spreading the fibers in the wound in my claims were surprising and unexpected in view of the state of the art evidenced by the references submitted with the application and cited by the Examiner.

I state that the claimed apparatus and method for drainage has been tested and used with excellent results that produced faster healing with reduced trauma. My flexible fiber drain has been used in patients undergoing both liposuction and breast reduction surgery. In these procedures, when the flexible fiber drain was used, a number of complications **did not** occur as frequently as expected. These include: fat stiffness, blue discoloration, seromas, and hematomas.

Bruising, swelling, and fat stiffness relate to the failure of removal of spent inflammatory fluids. In the early hours of wound healing, inflammatory fluids are useful in "glueing" the wound together with fibrin, and promoting clotting and debris removal. Once these processes are complete, these inflammatory fluids can become harmful, because of retained kinins and other toxic inflammatory substances, which irritate fat and can cause late oozing from blood vessels. These harmful changes are seen as bruising, swelling, and fat stiffness, which are caused by irritation of the tissue, and frequently result in breakdown of the skin and other severe healing problems.

In our study of 371 patients and 741 operative sites, my flexible fiber drains were placed at the time of operation and left in place for 3-5 days. The fibers were composed of harmless absorbable material similar to absorbable surgical sutures. The flexible fibers were introduced using a surgical clamp. Commercial drain "introducers" are available, but were not used because of the added expense. My flexible fiber drains caused no discomfort during the time that they were in place.

Compared to the largest published study of breast reduction in the plastic surgery literature, called the BRAVO study, the complication rate using my flexible fiber drain was much lower. In the BRAVO study suction drains were used.

I refer to the attached DRAIN PHOTOS which detail the placement of flexible fibers for drainage of a wound in a patient:
Figure 1. shows the flexible fibers attached to a cottonoid sponge.
Figure 2. demonstrates the placement of the catheter using a surgical clamp.
Figure 3. shows the flexible fibers held up after being passed through the skin.
Figure 4. points to the flexible fibers which are spread out to facilitate drainage.
Figure 5. shows the cottonoid sutured to the skin.

The BRAVO study was conducted by the American Society of Plastic Surgeons, using multiple plastic surgeons and sites. The results and complications of breast reduction were uniformly recorded for the first time in a multi-center study. The participating surgeons were not required to use a uniform method, such as a specified wound drain, but their combined results and complications represent the "state of the art" in reduction mammaplasty.

The results using my flexible fiber drain are significantly better than the BRAVO results, the patient population is much larger, and the size of the breast reductions in our study was 50% larger than the BRAVO study. This is very significant, since large breast size was identified in the latter study as the most significant risk factor for complications, particularly wound healing problems.

It is my opinion that my flexible fiber drain contributed to the more favorable results in our study. The data in the table that follows represent actual results found during surgeries and recovery. The BRAVO study (using suction drains) is depicted on the left side of the table, and it can be compared to my flexible fiber drains, which are labeled "Fiber Drain Study":

	BRAVO Study	Fiber Drain Study
Number of patients	179	371
Number of sites	358	741
Average resection	814 gm.	1200 gm.
Hematomas	3.7%	1.5%
Seromas	1.2%	0.5%
Infection	1.2%	1%
Delayed healing	22%	4%

The results with my flexible fiber drain are better than the results in the BRAVO study, in regard to seromas, hematomas, and delayed healing. This is remarkable, because of the larger breast size in the Fiber Drain Study. Consequently, my flexible fiber drain study should have been associated with much worse results, rather than better results found. Clotting of the cylindrical drain is expected after several days. Clotting was not a problem with the flexible fiber drain.

I believed that the references disclose systems that could not be modified to render obvious my claimed drain because they all seek to have an cylindrical opening remain open for drainage and do not appreciate that flexible fibers used as the drain without any surrounding structures or tubing are capable of guiding the drainage without unneeded trauma by holding an exit site open.

My flexible fiber drains are just as effective as tubes in removing liquids from the internal wound, and contribute to improved surgical wound healing. Unlike all cylindrical suction drains, flexible fiber drains do not cause any discomfort while in place or when the drain is removed.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true, and that the foregoing statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that my willful false statements or the like may jeopardize the validity of the above-identified patent application or any patent issued thereon.

Date February 5, 2006

John B. McCraw, M.D., F.A.C.S.